

*REMARKS/ARGUMENTS**The Pending Claims*

Claims 1-3, 5-6, 14-20, 28, 49-54, 62-64, 67-71, 76-81, 86-90, 98, 110, 112, 113, 116, 117, and 120-127 are pending. Of these, claims 1-3, 5-6, 14-20, 28, 49-51, 53, 54, 62-64, 67, 88-90, 98, 110, and 120-127 are directed to conjugates or compositions comprising conjugates, and claims 68-71, 76-81, 86, 87, 112, 113, 116, and 117 are directed to methods of using the conjugates.

Pending claims 5, 19, 53, 68-71, 76-81, 86, 87, 89, 112, 113, 116, and 117 have been withdrawn from consideration pursuant to the restriction requirement. Applicants request the rejoinder of withdrawn product claims to the extent they fall within the scope of an allowable generic "linking" claim. Applicants further request rejoinder of withdrawn method claims directed to the use of the subject matter of an allowable product claim.

The Office Action

The Office Action objects to the specification as containing a typographical error in the sequence at paragraph [0042]. The Office Action rejects former claims 1-4, 6, 14-18, 20, 28, 49-52, 54, 62-64, 67, 88, 90, 98, 99, 101, 110 and 111 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Office Action also rejects claims 99 and 101 under 35 U.S.C. § 102(b) as allegedly anticipated by Czerwinski et al. (*PNAS*, 95: 11520-11525 (1998)).

Reconsideration of these objections and rejections is hereby requested.

Amendment to the Specification and Sequence Listing

The specification has been amended to correct a typographical error in a sequence presented on page 13, paragraph 0042. A replacement sequence listing also is submitted herewith to correct the same error. No new matter has been added by way of these amendments.

Amendments to the Claims

Consonant with the restriction requirement, independent claims 1, 15, 49, and 88 have been amended to recite a ligand that binds to a gastrin receptor. Claims 4, 7-13, 18, 21-27, 52, 55-61, 91-97, 99-109, 111, 114-115, and 118-119 have been cancelled. New claims 120-127 have been added, which are directed to additional aspects of the invention. The new claims are supported by the specification, for example, at paragraph [0019]. No new matter has been added by way of these amendments.

Discussion of the Written Description Rejection

The Office Action rejects claims 1-4, 6, 14-18, 20, 28, 49-52, 54, 62-64, 67, 88, 90, 98, 101, 110, and 111 as lacking adequate written description support. In principal part, the Office Action alleges that the scope of the original claims is overly broad with respect to the “ligand” and “cytotoxic agent” elements, and that the description of the specification does not provide adequate support for the breadth of the claims.

Applicants disagree with the rejection as it was applied to the original claims. One of ordinary skill in the art reading the application, together with the knowledge available in the art at the time of filing, would readily ascertain that Applicants were in possession of the full scope of the claimed subject matter as of the filing date. Nevertheless, in the interest of expediting the prosecution of this application, Applicants have amended the claims.

As amended, the claims are directed to a conjugate comprising a ligand, one of several defined linkers, and a cytotoxic agent, wherein the ligand specifically binds to a gastrin (CCKB) receptor. Each element of the claims is described in the present application in a manner consistent with Section 112.

With respect to the ligand, the gastrin (CCKB) receptor was well-characterized and known to those of ordinary skill in the art as of the filing date, as were ligands to the receptor. Thus, a ligand that binds the gastrin receptor need not be described in detail in order to meet the requirements of Section 112. *See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986); *see also Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1085 (Fed. Cir. 2005). Nevertheless, several species of ligands that bind to a gastrin (CCKB) receptor are disclosed in the present application and

recited in dependent claims (e.g., paras [0015]-[0016] and claims 5, 6, 19, 20, 53, 54, 89, and 90).

With respect to the linker, each claim recites the sequence of the linker motif with particularity. Thus, there should be no issue as to the written description of this element.

As for the cytotoxic agent, the claims are not limited to any particular cytotoxic agent. Cytotoxic agents were commonplace at the time the present application was filed. Furthermore, the examples provide specific guidance as to the use of a variety of different cytotoxic agents. Given the description provided in the present application, those of ordinary skill in the art would have appreciated that a variety of cytotoxic agents could be linked to the linker motif and used in the invention.

In view of the foregoing, Applicants believe that the claimed subject matter is adequately described such that one of ordinary skill in the art would be on notice that Applicants were in possession of the full scope of the claimed subject matter at the time of filing. Accordingly, Applicants respectfully request that the Section 112 rejection of the claims as lacking written description be withdrawn.

Discussion of the New Claims

New claims 120-127 are directed to conjugates comprising specific cytotoxic agents in combination with specific ligands. Applicants submit that the new claims are in compliance with Section 112.

Discussion of the Prior Art Rejection

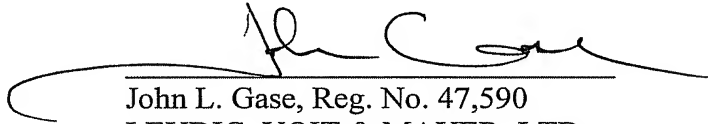
The Office Action indicates that the various linker sequences presented in the claims conjugated to SEQ ID NO: 20 are free of the prior art, and that the search and examination was expanded to include the generic claims. The Office Action presents only a single prior art rejection of claims 99 and 101 over Czerwinski et al. No prior art rejection of the remaining claims has been made.

Applicants disagree with the prior art rejection of claims 99 and 101. However, all of claims 99-109 have been cancelled rendering the rejection moot.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John L. Gase", is written over a horizontal line.

John L. Gase, Reg. No. 47,590
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
180 North Stetson Avenue
Chicago, Illinois 60601-6731
(312) 616-5600 (telephone)
(312) 616-5700 (facsimile)

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